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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/753,630	01/02/01	HOSSAINY S	M-8618 US

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EXAMINER	
KOLB, J	
ART UNIT	**PAPER NUMBER**
1762	4

DATE MAILED: 07/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/753,630	Applicant(s) HOSSAINY ET AL.
	Examiner Jennifer Kolb	Art Unit 1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *12-14,19-21 and 26-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-11,15-18 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-11, 15-18, 22-25, drawn to a method, classified in class 427, subclass 2.1+.

   II. Claims 12-14, 19-21, 26-28, and 35-36, drawn to a product, classified in class 604.

   III. Claims 29-34, drawn to a composition, classified in class 106.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as by co-extruding the medical device with the layers.

Inventions III and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the

product as claimed can be practiced with another materially different product, such as a polymer composition including a polymer other than EVA copolymer and a solvent other than THF, for example using heparin and PEG in aqueous solution.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and effects. The medical device product and the composition product are used for different purposes and functions.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Groups I, II, and III are not required for each of the others, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Cameron Kerrigan on July 3, 2001 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11, 15-18, and 22-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12-14, 19-21, and 26-36 are withdrawn from

further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

primer adhesion, barrier, topcoat,

9. Claims 1-2, 4, 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhong.

hep
coat

Zhong teaches coating an implantable medical device with a bio-compatible coating containing polyurethane. Such a coating can serve as a topcoat or serve as a primer for a second coating layer that contains certain bio-active agents (abstract, col. 1, line 14). After application of the coating, it is dried at a temperature up to 120 °C, or higher in the case of a metal substrate, to attach the coating to the substrate (col. 3, line 60 and col. 8, lines 18 and 32). When used as a primer, the coating contains organic acid

functional groups, such as carboxyl groups, reactive with subsequently applied thrombo-resistant agents (paragraph bridging cols 3 and 4 and col. 4, line 52). Zhong teaches that all layers may be applied by dipping (col. 6, lines 34 and 67). The bio-active agent of the second coating may be a thrombo-resistant agent, such as heparin or hyaluronic acid (col. 7, lines 14-28). Further, Zhong teaches that multiple layers of the polyurethane-containing coating may be used alone or in combination with multiple layers of the bio-active agent coatings.

Since Zhong teaches the use of multiple layers of the bio-active containing coating, the limitations of claim 2 are met.

Since Zhong teaches the use of the polyurethane-containing coating, the limitations of claim 4 are met.

primer EVAL

10. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tuch.

Tuch teaches a method of making a blood-contacting medical device with biocompatibility by applying multiple thin coats of heparin in solution to the medical device (abstract and col. 3, line 18). The multiplicity of coats act as the primer, first hemocompatible coating, and second hemocompatible coating, all containing heparin, as required in claims 1, 2, 4, and 5. Because the heparin is provided as a therapeutic dosage, it is inherently releasable into the blood. Further, the coatings must inherently be "sufficiently tightly bonded" to the surface or they would be ineffective for implants.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 3, 18, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Hostettler et al. '960

Zhong teaches that which is disclosed above, but fails to teach roughening the surface of the substrate prior to coating.

Hostettler teaches roughening of a medical substrate prior to applying polyurethane-based coatings (col. 13, line 47). Since Zhong and Hostettler teach application of polyurethane-based coatings to medical devices and Hostettler teaches pre-treatment by roughening the substrate, Hostettler would have reasonably suggested roughening the surface of Zhong's device prior to coating. It would have been obvious to one of ordinary skill in the art to use the teachings of Hostettler in the method of Zhong to roughen the surface of Zhong's substrate prior to coating to increase the surface area of the substrate and thus enhance adhesion of the coating.

In regard to claim 22, while Zhong does not teach "baking" the substrate, he does teach a heat treatment step which would be inclusive of baking. Baking occurs at a temperature up to 120 °C, or higher in the case of a metal substrate, overlapping the range set forth by the Applicant. Overlapping ranges are *prima facie* evidence of

obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Zhong's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

In regard to claim 25, Hostettler teaches argon plasma pre-treatment which will inherently act as the roughening argon plasma pre-treatment step required by Applicant (col. 16, line 16).

13. Claims 15-18 and 22-24 rejected under 35 U.S.C. 103(a) as being unpatentable over Fox, Jr. et al.

Fox, Jr. et al. teach a method of preparing an infection resistant medical device by dip coating with a composition of polyurethane and heparin (abstract, col. 2, and col. 14, lines 51 and 56). The coating is then dried at an elevated temperature, which would be inclusive of baking. It would have been obvious to one of ordinary skill in the art to select "baking" as a method of drying a substrate at an elevated temperature.

While Fox, Jr. et al. fail to specifically teach a roughening pre-treatment step, Examiner takes Official notice that it is customary in the art to roughen a substrate prior to coating to enhance adhesion. While the reference does not provide a specific drying temperature, it is Examiner's position that selection of a cause-effective variable such as temperature is within the skill of one practicing in the art. It would have been obvious to one having ordinary skill in the art to have determined the optimum values of the relevant process parameters through routine experimentation in the absence of a showing of criticality. *In re Aller*, USPQ 233 (CCPA 1955).

14. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hostettler '656.

Hostettler '656 teaches a method of coating medical devices with tenaciously adhering coatings of polyurethane that are biocompatible and long-lasting in blood (abstract). Prior to coating with the polyurethane-based coating, Hostettler teaches application of an aminosilane primer to the surface (col. 14, lines 27-34), such as trimethoxysilane. Hostettler teaches that the polyurethane coating includes polysaccharides, but fail to specifically teach the use of heparin. Heparin is a polysaccharide commonly used in medical device coatings as it provides thromboresistant properties. The teaching of polysaccharides as a broad class would be inclusive of heparin and it would have been obvious to one of ordinary skill to select heparin as a suitable and useful polysaccharide in the method of Hostettler. Further, Hostettler discloses the use polysaccharides, such as heparin, as a coating for amine-treated medical devices in the prior art (col. 4, line 52).

Hostettler teaches the application of two coats of the polyurethane hydrogel (Example 6) coatings containing polysaccharide, forming the first and second hemocompatible coatings. Hostettler teaches roughening of the substrate prior to application of the primer (col. 10, line 28).

15. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hostettler '656 in view of Nygren et al.

Hostettler teaches that which is disclosed above, including the use of aminosilane primers, but fail to teach the use of chlorosilane, specifically, as the primer.

Nygren et al. teach the attachment of a polysaccharide, such as heparin, via a chlorosilane coupling group containing an epoxy. Since Hostettler teaches the use of amine coupling primers for subsequent attachment of polysaccharides and Nygren teaches the use of chlorosilane as a coupling agent for subsequent attachment of a polysaccharide, Nygren would have reasonably suggested the use of chlorosilane as the silane in the method of Hostettler. It would have been obvious to one of ordinary skill in the art to interchange the chlorosilane of Nygren with the aminosilane of Hostettler with the expectation of similar, successful results. The functional head of Nygren's chlorosilane appears to be "unsaturated".

In regard to claim 9, Hostettler teaches the use of polyethylene glycol (table I) as part of the hydrogel composition. Therefore, the functional groups present on the primer will be modified by attachment to the polyethylene glycol applied in subsequent coatings.

In regard to claims 10-11, Hostettler teaches that the double coating of the hydrogel may comprise additional polyurethane hydrogel polymers having the original or different compositions, which would inherently give varying coating properties.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb
July 16, 2001

SHRIVE P. BECK
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